

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/019,949	NAKASHIMA ET AL.
	Examiner Gailene R. Gabel	Art Unit 1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to Applicant's amendment filed on May 16, 2007 and Interview Summary on June 8, 2007.
2.  The allowed claim(s) is/are 1, 5-10, and 15-17; now renumbered as claims 1, 5-7, 2-4, and 8-10, respectively.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date October 6, 2004.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application
6.  Interview Summary (PTO-413),  
Paper No./Mail Date June 8, 2007.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.



*Gabel*  
6/11/07

**EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Tom Siepmann on June 8, 2007.

***Drawings***

2. New corrected formal drawings in compliance with 37 CFR 1.121(d) are required in this application because claims 1, 5-10, and 15-17 are allowed. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected formal drawings will not be held in abeyance.
3. The application has been amended as follows:

In claim 1, line 1 in the preamble, after "An immunoassay for assaying a", "soluble" has been deleted.

In claim 1, line 2 in the preamble, after "antibody present in", --serum or plasma portion of-- has been inserted.

In claim 1, step a) line 2, after "with an antigen against the", "soluble" has been deleted. Further after "or an antibody against the", "soluble" has been deleted.

In claim 1, step f) line 1, after "a concentration of the", "soluble" has been deleted. Further in line 3 after "a concentration of a", "soluble" has been deleted.

In claim 1, step g) line 1, after "a concentration of the", "soluble" has been deleted. Further in line 4 after "the concentration of the", "soluble" has been deleted.

In claim 1, step g) line 5, after "antigen or antibody present in the", --serum or plasma portion of-- has been inserted.

In claim 5, line 1 in the preamble, after "An immunoassay for assaying a", "soluble" has been deleted.

In claim 5, line 2 in the preamble, after "antibody present in", --serum or plasma portion of-- has been inserted.

In claim 5, step a) line 2, after "an antigen against the", "soluble" has been deleted. Further after "or an antibody against the", "soluble" has been deleted.

In claim 5, step f) line 1, after "a concentration of the", "soluble" has been deleted. Further in line 3 after "a concentration of", "soluble" has been deleted.

In claim 5, step g) line 2, after "concentration of the", "soluble" has been deleted.

Claim 7 has been amended as follows:

--The immunoassay according to claim 5, wherein correction according to the MCV measurement and the number of blood cells is made by use of the following formula:

C = CO / {1-(B/A) X (MCV / D)},

-wherein C is a corrected concentration, CO is the concentration of the target antigen or the target antibody present in the serum or plasma portion of whole blood sample, A is a constant, B is the number of blood cells, MCV is the MCV measurement of the sample, and D is a constant.--

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1641

Gailene R. Gabel  
Primary Examiner  
Art Unit 1641



June 8/2007

11